A Section 508–conformant HTML version of this article is available at https://doi.org/10.1289/EHP11096.

Invited Perspective: Household Air Pollution—Can Randomized Controlled Trials Provide the Answers to Complex Intervention Questions?

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https://doi.org/10.1289/EHP11096

Refers to https://doi.org/10.1289/EHP9932

Worldwide, roughly 3.8 billion people heat or cook with wood and other solid fuels,[1] which exposes them to numerous household air pollutants associated with ill health.[2] Household air pollution exerts an immense toll on human health, contributing to an estimated 2.31 million deaths in 2019. Although rural U.S. populations have lower average ambient exposures to particulate matter ≤ 2.5 μm in aerodynamic diameter [fine PM ($PM_{2.5}$)] than urban populations,[3] rural homes that are heated with woodstoves have higher exposure to indoor air pollution than those that use other sources of heating, such as electricity.[4] Of the 12.5 million U.S. homes that burn wood for space heating, 3.5 million use woodstoves as the primary source of heating.[5] For homes that use inefficient woodstoves, indoor levels of $PM_{2.5}$ can exceed the U.S. Environmental Protection Agency National Ambient Air Quality Standard of $<35\ \mu g/m^3$ over a 24-h period.[4,6,7,8] Given that $PM_{2.5}$ exposure is associated with adverse health effects, such as child lower respiratory tract infections (LRTIs),[2] it is important that people who heat their homes with wood not only have access to interventions that reduce these household exposures, but also that they use them consistently and correctly.

The Kids Air Quality Interventions for Reducing Respiratory Infections (KidsAIR) study is a parallel three-arm (education, portable air filtration unit, control groups) randomized controlled trial to reduce incidence of child LRTI in households that use woodstoves for heating.[9] KidsAIR was conducted at three sites: Alaska Native communities in Alaska, rural communities in Montana, and Navajo communities on the Navajo Nation (Arizona and New Mexico). In this issue of *Environmental Health Perspectives,* Walker et al. report that although the intention-to-treat results were not statistically significant, an exposure–response analysis indicated that the odds of LRTI were 1.45 times higher [95% confidence interval (CI): 1.02, 2.05] per interquartile range increase in mean indoor $PM_{2.5}$.[10]

The KidsAIR study is unique in that the preponderance of research on household air pollution has been conducted in settings outside of the United States. Yet nearly 10% of U.S. households use wood for primary or secondary heating. Of those households that use wood for primary heating, over half report an annual income of less than $60,000 and live in a cold or very cold region.[11] In Navajo County, Arizona, where 44% of the population is Native American, 28% of households use wood for heating.[12] By recruiting from rural and American Indian/Alaska Native communities, this study makes an important contribution to highlighting environmental health inequities among rural U.S. populations that use woodstoves for heating.

One major strength of the KidsAIR study is its commendable diagnostic specificity; a pediatric pulmonologist conducted a rigorous masked assessment of LRTI by reviewing medical charts, and health technicians conducted in-home prospective assessments. Another commendable strength of this study is the implementation of community advisory boards to shape the trial, including input on the development of educational materials, inclusion of households with tobacco smokers, and the implementation of control arm procedures. For example, at the Alaska study site, the community advised against the use of a sham filtration unit in the control arm. Although including smokers may confound the effect of air pollution on LRTI, and a lack of a placebo may lead to a host of biases, the investigators demonstrated a commitment to community feedback. Their sensitivity analyses, assessing the effects of smoking by allowing the inclusion of household smokers, and exclusion of the Alaskan subgroup, found that these factors did not appreciably change the study findings.

From 2002 to 2005, I worked on the Randomized Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE) in Guatemala. The late Dr. Kirk R. Smith established this randomized controlled trial of a wood-fueled chimney cookstove in rural Indigenous Mam Mayan households in the Western Highlands of Guatemala. In an intention-to-treat analysis, the stove intervention was associated with a 22% reduction in physician-diagnosed child pneumonia, but, as in the KidsAIR study, the findings were not statistically significant (95% CI: –6%, 41%). However, an exposure–response analysis did show that a 50% decrease in exposure to household air pollution, specifically carbon monoxide, was associated with a 28% reduction in child pneumonia (relative risk = 0.82; 95% CI: 0.70, 0.98).[13] These results prompted support for the Household Air Pollution Intervention Network (HAPIN) trial, this time providing clean-fuel stoves that would radically improve indoor air quality in 3,200 households in Guatemala, India, Rwanda, and Peru.[19]

The randomized controlled trial is the gold standard for assessing causality; however, interventions at the household level under real-world conditions are complex and can lead to null findings for many reasons, one of which is fidelity to the intervention.[14] Although the KidsAIR study paid electrical costs in participating homes, the median use of the air filtration unit was only 56% of the expected kilowatt hours, demonstrating low compliance with the intervention. The authors did not discuss efforts to encourage adherence to the filtration units, but low compliance could have reduced the strength of effect. The authors stated that as compliance increased over the 6-d period of measure, indoor $PM_{2.5}$ did not decrease. This seems counterintuitive because the purpose of the trial was to reduce $PM_{2.5}$ using an air filtration unit. Furthermore, even if the participants complied during the 6-d period of measure, does this accurately represent $PM_{2.5}$ exposures and compliance with the intervention when the investigators are not present? A single 6-d sampling period may not represent the long-term exposures over a 2-y observation

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The author declares she has nothing to disclose.

Received 11 February 2022; Revised 16 March 2022; Accepted 18 March 2022; Published 8 April 2022.

period if other activities, such as smoking in study households, occur between measurement periods.

Ongoing behavioral reinforcement might have increased filtration unit use. For example, in the HAPIN trial, we augmented the delivery of a new cookstove with a careful assessment of fidelity to the intervention, applying stove use temperature sensors that provided feedback to local personnel.[15] If an intervention home continued to use a biomass stove instead of, or in addition to, the liquified petroleum gas (LPG) stove, we arranged behavioral reinforcement visits to ascertain why and encourage use of the new unit.[16]

Despite the null findings presented in the KidsAIR intention-to-treat analysis, the exposure–response analysis showed an association similar to that seen in the RESPIRE trial.[13] We know from decades of human and animal studies that there is an established association between exposure to air pollution and adverse health outcomes. We also know a great deal about barriers that impede people's adoption and continued use of interventions.[17] Randomized controlled trials will continue to be the gold standard, and each "unsuccessful" intervention will inevitably be dissected to understand the factors that may have led to null findings. However, perhaps it is time to consider effectiveness studies in reducing household air pollution, using an implementation research approach, to assess how people interact with interventions, how interventions are adopted, and how they are sustained in complex settings.[18]

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